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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,512	05/05/2000	MICHAEL ANTHONY JOHNSON	2-00US	2004

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GREENLEE WINNER AND SULLIVAN P C  
5370 MANHATTAN CIRCLE  
SUITE 201  
BOULDER, CO 80303

EXAMINER

WINKLER, ULRIKE

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 10/01/2002 20

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/485,512

Applicant(s)

JOHNSON ET AL.

Examiner

Ulrike Winkler, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,25-32 and 39-62 is/are pending in the application.
- 4a) Of the above claim(s) 45-50 and 52-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,25-32,39-44 and 51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

The Amendment filed July 9, 2002 (Paper No. 19) in response to the Office Action of January 30, 2002 is acknowledged and has been entered. Claims 3, 5-24 and 33-38 have been cancelled. Claims 43-62 have been added. Claims 1, 2, 4, 25-32, 39-44 and 51 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### ***Election/Restrictions***

During a telephone conversation with Ellen Winner on September 17, 2002 a provisional election was made with traverse to prosecute the invention of Group 6, claims 43, 44 and 51. Affirmation of this election must be made by applicant in replying to this Office action. Claims 45-50 and 52-62 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

1. Claims 43, 44, 45, drawn to an immunopotentiating molecule.
2. Claims 43, 44, 46, drawn to antigenic determinants of infectious agents causing intestinal diseases in pigs.
3. Claims 43, 44, 47, drawn to an antigenic polypeptide which encodes antigenic determinants of infectious agents causing respiratory diseases in pigs. .
4. Claims 43, 44, 48, 49 drawn to an antigenic polypeptide which encodes an antigenic determinant of pseudorabies virus.
5. Claims 43, 44, 50, drawn to an antigenic polypeptide which encodes an antigenic determinant of porcine respiratory and reproductive syndrome virus.
6. Claims 43, 44, 51, drawn to an antigenic polypeptide which encodes an antigenic determinant of Hog cholera virus.
7. Claims 43, 44, 52, drawn to an antigenic polypeptide which encodes an antigenic determinant of porcine parvovirus.
8. Claims 43, 44, 53, drawn to an antigenic polypeptide which encodes an antigenic determinant of porcine coronavirus.
9. Claims 43, 44, 54, drawn to an antigenic polypeptide which encodes an antigenic determinant of porcine rotavirus. .

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10. Claims 43, 44, 55, drawn to an antigenic polypeptide which encodes an antigenic determinant of porcine parainfluenza virus.
11. Claims 43, 44, 56, drawn to an antigenic polypeptide which encodes an antigenic determinant of *Mycoplasma hyopneumonia*.
12. Claims 43, 44, 57, drawn to an antigenic polypeptide which encodes FLT-3 ligand.
13. Claims 43, 44, 58, drawn to an antigenic polypeptide which encodes interleukin-3 (IL-3).
14. Claims 43, 44, 59, drawn to an antigenic polypeptide which encodes porcine interleukin-4 (IL-4).
15. Claims 43, 44, 60, drawn to an antigenic polypeptide which encodes gamma interferon.
16. Claims 43, 44, 61, drawn to an antigenic polypeptide which encodes porcine granulocyte macrophage colony stimulating factor (GM-CSF).
17. Claims 43, 44, 62, drawn to an antigenic polypeptide which encodes porcine granulocyte colony/ stimulating factor (G-CSF).

Claims 43 and 44 link(s) inventions 1-17. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 43, 44. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

***Specification***

The office acknowledges the receipt of the newly formatted table 2 in the specification.

***Drawings***

The drawings have been approved by the drafts person.

***Claim Rejections - 35 USC § 112***

The rejection of claims 31, 32 and 39 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn**.

The rejection of claims 40-42 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is maintained** for reason of record. It remains unclear what is intended with "at least one heterologous sequence" does this include a promoter plus a sequence or does this require two complete heterologous sequences.

***Claim Rejections - 35 USC § 103***

The rejection of claims 1, 2, 4, 25-32 and 39-42 and newly added claims 43 and 44 under 35 U.S.C. 103(a) as being unpatentable over either Callebrant et al. (Coronaviruses 1994, see IDS paper No. 6) or Torres et al. (Journal of Virology 1996, see IDS paper No. 6) and either

Kleiboeker (Virus Research, 1994, see IDS paper No. 6) or Reddy et al. (Virus Research 1996, see IDS paper No. 6) is **maintained** for reasons of record.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., greater than 105% the size of wild type adenovirus) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore even if the limitation were inserted into the claims the mere recitation of the limitation "greater than 105% the size of wild type adenovirus" is not sufficient to overcome the rejection as it is known in the art that adenovirus allows packaging of approximately 105% of normal genome (see Field's Virology, p2166), "approximately" interpreted as including sizes greater than 105%.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant argues that the E3 region of the porcine adenovirus is smaller than that of the human adenoviruses. It is important to point out that although there may be differences in the specific sequences between the viruses, which would account for their limited host range. All the viruses discussed in the references belong to the family Adenoviridae. In order for a virus to be placed into a "family" a virus must share certain features which include, morphology, physiochemical and physical properties, genome organization and replication including number and position of the open reading frames,

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the functional and structural properties of the proteins, lipid content, the site and nature of virion maturation and release. To reiterate each of the references suggest making a vaccine for the immunization of pigs against disease that are important for the pork industry. Two of the references utilize human adenovirus for the development of porcine vaccines, because the viruses belong in the same family and therefore share important structural and functional features the ordinary artisan would have had a high expectation success in utilizing the teachings from the human adenoviral vectors vaccine and apply the same construction for the expression of a heterologous sequence in a porcine adenovirus. The teachings in the prior art regarding the porcine adenovirus DNA structural features of the E3 region would have provided the ordinary artisan with the road map to make the claimed porcine adenoviral vectors for the insertion of a heterologous sequence especially since the reference suggest this. Therefore, the instant rejection is maintained.

Claim rejection in view of applicants amendment:

The rejection of claims 1, 2, 4, 25-32 and 39-42 and newly added claims 43, 44 and 51 under 35 U.S.C. 103(a) as being unpatentable over either Callebrant et al. (Coronaviruses 1994, see IDS paper No. 6) or Torres et al. (Journal of Virology 1996, see IDS paper No. 6) and either Kleiboeker (Virus Research, 1994, see IDS paper No. 6) or Reddy et al. (Virus Research 1996, see IDS paper No. 6) and further in view of Koneig et al. (Journal of Virology, 1995).

The relevance of Callebrant et al., Torres et al, Kleiboeker and Reddy et al. has been discussed above and in the prior office action. The combined references teach the insertion of heterologous nucleotide sequences into an adenoviral genome for the expression of the

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nucleotide sequence as a vaccine. The references also provide the nucleotide sequences for the porcine adenoviral E3 region that is the adenoviral gene segment that can accommodate the heterologous nucleotide sequences. The references do not teach immunization against hog cholera virus (a.k.a. classical swine fever virus) or insertion of an immunogenic portion of Hog cholera virus into a recombinant virus for use as a vaccine. Koneig et al. teach the production of a recombinant vaccinia virus construct that encodes sequences of the classical swine fever virus. The viral construct is used to protect pigs against Hog cholera virus (see p. 6483 , column 2). The reference teaches which structural proteins will provide protective immunity against hog cholera virus. The reference does not teach inserting the constructs into an adenoviral vaccine vector. It would have been obvious to one of ordinary skill in the art at the time the invention was made to insert a known construct that provides protective immunity into an adenoviral vector for the production of a vaccine. One having ordinary skill in the art would have been motivated to do this because adenoviruses do not cause serious illness in the animal and they do not pose serious risk to laboratory personnel manipulating the virus. Therefore, given what is known in the art regarding the construction of adenoviral vectors and the knowledge of structural proteins that provide protective immunity against hog cholera virus in an animal the ordinary artisan would have a high expectation of success when inserting the Hog cholera virus structural proteins into an adenoviral vaccine vector. Therefore the instant invention is obvious over Callebrant et al., Torres et al, Kleiboeker and Reddy et al. in view of Koneig et al.

### ***Conclusion***

No claims are allowed.



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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

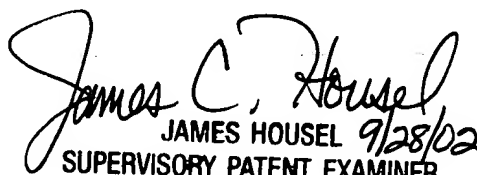
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D.

  
JAMES HOUSEL 9/28/02  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600